REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As indicated in the Office Action Summary, claims 1-25 are pending. Claims 11-22 stand withdrawn. The specification is amended herein to address formality issues with regard to trademarks. Thus, no new matter is submitted herein.

Priority

As requested by the Office, a certified translation of the priority document, Swedish Application No. 0200667-7, filed March 5, 2002, is attached hereto.

Specification

The Office notes the use of the trademarks Apozepam, Mebumal Vet, Hypnodil, Ketalar, Stersnil, Humicade, Roquininex, Ariflo, Orthegen, Orthokin in the specification and requires that they be capitalized and be accompanied by the generic terminology, as needed. The specification is amended in this regard. Thus, this objection is obviated.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-10 and 23-25 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the enablement requirement. Applicant notes with appreciation that the subject matter as directed to methods for reduction of

scar tissue and/or adhesion formation is considered enabled by the Office. The Office asserts that the methods for prevention of scar tissue are not enabled. Applicant traverses.

Applicant submits that undue experimentation would not be required to practice the methods of prevention of scar tissue and adhesion formation, as claimed herein.

First, in the context of the present invention. as used in the present specification, Applicant notes that "prevention" refers to the administration of a substance at the time of injury in order to eliminate the possibility of scar tissue occurring. Thus, the unwanted event prevented by the claimed methods is the development of scar that will compress the adjacent nerves and the development of adhesion between intra spinal and the scar or other intra spinal structures.

Applicant further notes that the scar formation of the present invention is a pathologic condition which often occurs following spinal surgery. Such a scar is organized and fibrotic, and compresses the adjacent nerves, producing pain. This condition is also referred to as "epidural scarring" or "fibrosis". Thus, Applicant notes that the scar tissue of the present invention is different from scars which are the normal result of skin and muscle healing. In fact, the preventive effects of the present methods are similar to the reductive effects.

Applicant submits that the skilled artisan could practice the claimed preventative methods using the present specification. In the Example of the present specification, it is disclosed that the rats treated with a substance according to the claimed methods, (infliximab), developed only soft connective tissue rather than

developing a "dense lump" as in the control rats. This difference is clear and significant.

It would be clear to the skilled artisan how to practise the present invention. According to the Example provided in the specification, the risk for the treated rats to develop scarring is much less likely. For a spinal surgeon, the results and the potential of the invention are evident.

Applicant further notes as discussed in the Example, there were no adhesions between the intra spinal nerves and surrounding structures in the treated animals. In contrast, the control animals displayed marked adhesions between the "dense lump" and the nerves. The control rats were exposed to a situation that is normal following spinal surgery. The absence of a "dense lump" and adhesions in the treated rats is unexpected and important in preventing epidural scarring.

As the specification provides a clear example describing how to practice the prevention of scar tissue and adhesion formation, Applicant submits that the skilled artisan could practise the present invention without undue experimentation, as with the reduction of scar tissue also claimed and acknowledged by the Office as enabled.

Applicant requests that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Rejections Under 35 USC §102

Claims 1-10 and 23-25 stand rejected under 35 U.S.C. § 102(e) as purportedly anticipated by Reuben *et al.* (United States Patent Publication No. US 2002/0072596) ("Reuben").

To anticipate a claimed invention under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Lindeman Machinenfabrik GmbH v. American Hoist and Derrick Company*, 221 USPQ 481, 485 (Fed. Cir. 1984). Applicants submit that Reuben does not disclose each element of the claims, nor is Reuben enabling for the present claims.

Reuben discloses transferrin sequences, two of which (SEQ ID NO:4 and SEQ ID NO:6) can be derived from the lactoferrin molecule. However, Reuben does not disclose sequences with complete lactoferrin sequence homology. The protein chain of human lactoferrin is folded into two globular lobes, the so-called N- and C-terminal lobes. SEQ ID NO 4 and SEQ ID NO 6, as disclosed in Reuben, appear to resemble lactoferrin sequences belonging to the C-lobe.

In contrast, the present invention is directed to sequences relating either to the entire lactoferrin molecule, or to the lactoferrin peptides belonging to a fragment of the N-lobe (see attached Exhibit A, by way of explanation). Exhibit A shows a modelling of human lactoferrin, and illustrates that the peptides of the present invention are from the N-lobe of the human lactoferrin protein.

To this end, Applicant notes that the properties of the peptide sequences in the C-lobe and the N-lobe are significantly different. The N-lobe of the lactoferrin molecule contains positively charged surface structures, which possess biological activities (*i.e.* microbicidal activity, binding to LPS, heparin, and heparansulphate, anti-inflammatory activity). These properties are not present in the C-lobe or in peptides from the C-lobe. Thus, the biological activity of the lactoferrin molecule is greatly determined by the interaction of the charged regions in the N-lobe. Applicant further notes that there are also between the function of the complete lactoferrin

molecule and the function of peptides from the C-lobe. As a result, as the peptides of Reuben from the C-lobe have different activity from those peptides of the present invention from the N-lobe, practicing methods of Reuben is not practicing the elements of the claimed methods.

Reuben fails to recite each element of the present invention and is not enabled with regard to the present invention. Applicant requests that the rejections under 35 U.S.C. § 102 be withdrawn.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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EXHIBIT A

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